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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/676,045 | 09/30/2003 | Yaron Ilan | Enz-63(CIP) | 5995 |

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| EXAMINER | |
|---|---|
| SKELDING, ZACHARY S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | |

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/676,045 | ILAN ET AL. | |
| | Examiner | Art Unit | |
| | Zachary Skelding | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-39,41-111 and 113-142* is/are pending in the application.

4a) Of the above claim(s) *47-49, 64, 65, 73-82, 127-129 and 132-140* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39,41-111 and 113-142* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's Preliminary Amendment to the claims, filed October 24, 2003, is acknowledged.

   The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

   Claims 40 and 112 have been canceled.

   Claims 141 and 142 have been added.

   Claims 1-39, 41-111 and 113-142 are pending.

2. It is noted that claims 47-49, 64, 65, 73-82, 127-129 and 132-140 are directed to **"The use of..."** NKT cells or antibodies that bind NKT cells. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

   **Therefore, claims 47-49, 64, 65, 73-82, 127-129 and 132-140 have been withdrawn from consideration as being drawn to non-statutory subject matter.** If these claims are amended to recite statutory subject matter, the amended claims may be rejoined with the appropriate Groups as set forth below.

3. It is noted that claims 25-30, and many others are multiply dependent on claims which are themselves multiply dependent.

   Unless corrected, these claims will be objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim, and these claims will not be further treated on the merits. See MPEP § 608.01(n).

   Appropriate correction is required.

***Restriction Requirement***

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 83-95, 99 and 104, drawn to a method of treatment using **NKT cells** to **promote inflammation**, classified in Class 424, subclass 93.1.

II. Claims 3, 5-15, 19, 24 and 32, drawn to a method of treatment using **NKT cells** as an **anti-inflammatory**, classified in Class 424, subclass 93.21.

III. Claims 16-18, 20, 23, 96-98, 100 and 103, drawn to a method of treatment using **oral tolerization** to **elicit up or down regulation of the immune system**, classified in Class 424, subclass 184.1.

IV. Claims 21 and 22, drawn to a method of treatment using **NKT cells** as an **anti-inflammatory** further comprising using **oral tolerization** to **elicit up or down regulation of the immune system**, classified in Class 424, subclass 185.1.

V. Claims 33-39, 41-46 and 50-63, drawn to **ex-vivo educated NKT cells capable of acting as anti-inflammatory agents**, classified in Class 424, subclass 93.7.

VI. Claims 66-72, drawn to **antibody that recognizes NKT cells**, classified in Class 424, subclass 130.1.

VII. Claims 101 and 102, drawn to a method of treatment using **NKT cells** to **promote inflammation** further comprising using **oral tolerization** to **elicit up or down regulation of the immune system**, classified in Class 424, subclass 184.1.

VIII. Claims 113-126, 130 and 131, drawn to **ex-vivo educated NKT cells capable of acting as pro-inflammatory agents**, classified in Class 424, subclass 93.71.

5. **Claims 2 and 4 link Groups I and II.**

The restriction requirement between Groups I and II is subject to the nonallowance of the linking claim(s), claims 2 and 4.

**Claims 25-31 and 141 link Groups I-IV.**

The restriction requirement between Groups I-IV is subject to the nonallowance of the linking claim(s), claims 25-31 and 141.

**Claims 105-111 and 142 link Groups I, III and VII.**

The restriction requirement between Groups I, III and VII is subject to the nonallowance of the linking claim(s), claims 105-111 and 142.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Groups I-IV and VII are different methods, which differ with respect to one or more ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Further, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these inventions together.

7. Groups V, VI and VIII are different products. The products are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct, and searching of these Inventions would impose an undue burden.

8. Groups V and II/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, inflammatory immune diseases can be treated with agents other than NKT cells, for example, with corticosteroids.

9. Groups VIII and I/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, immune diseases requiring more inflammation can be treated with agents other than NKT cells, for example with an adjuvant.

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

***Species Election***

11. This application contain claims directed to the following patentably distinct species of the claimed invention:

12. If applicant elects any one of **Groups I-IV or VII** applicant is required to elect one specific **immune related or immune-mediated disorder** to be treated, for example, as recited in claim 23, "SLE" **OR** "Myasthenia Gravis" **OR**, for example, as recited in claims 41 and 45, "Non-alcoholic Steatohepatitis" **OR** "Graft Versus Host Disease".

    These pathological conditions are patentably distinct because they differ in etiologies and therapeutic endpoints. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

    Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

13. If applicant elects any one of **Groups I, II, IV, V, VII or VIII** applicant is required to elect **one** specific set of **culture conditions** for the ex vivo education of NKT cells from among the possibilities recited in, for example, claim 7,

    - wherein the elected **"antigen or epitope"** is chosen from, for example as recited in claim 9, "xenogenic antigens" **OR** "allogenic antigens obtained from donors suffering from said immune-related or immune-mediated disease"; **AND,**

    - wherein the elected **"liver-assoicated cell"** is chosen from, for example as recited in claim 10, "Kupffer cells" **OR** "Stellate cells"; **AND,**

    - wherein the **"cytokine or adhesion molecule"** is chosen from, for example as recited in claims 11 and 12, "IL4" **OR** "integrins".

    These molecules are patentably distinct because their structures, and/or physiochemical properties are different, and/or they do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

    Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

14. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and **a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

    In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

    Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zachary Skelding, Ph.D.
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June 16, 2006

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6/19/06